MOTION FILED

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No. 04-1047

IN THE

Supreme Court of the United States

WARNER-LAMBERT CO., *et al.*,

Petitioners,

v.

MARY ROSE WAKEFIELD,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE OKLAHOMA COURT OF CIVIL APPEALS

MOTION OF THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AND BUSINESS ROUNDTABLE FOR LEAVE TO FILE A BRIEF AS *AMICI CURIAE* IN SUPPORT OF PETITIONERS AND BRIEF *AMICI CURIAE*

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The Chamber of Commerce of the United States of America (the "Chamber") and Business Roundtable (the "Roundtable") hereby move pursuant to Supreme Court Rule 37.2(b) for leave to file the attached *amici curiae* brief in support of Warner-Lambert Company's and Pfizer Inc.'s petition for a writ of certiorari to the Oklahoma Court of Civil Appeals. *Amici* are filing this motion because consent to the filing of this brief was granted by counsel for Petitioners but denied by counsel for Respondent.

The Chamber is the nation's largest federation of business companies and associations, with an underlying membership of more than 3,000,000 businesses and professional organizations of every size and in every sector and geographic region of the country. Because the fair administration of punitive damages long has been a concern of the business community, the Chamber regularly files *amicus* briefs in punitive damages cases. It is the Chamber's experience that the lower courts routinely have been misapplying and effectively nullifying the principles identified by this Court in *BMW of North America, Inc. v. Gore*, 517 U.S. 559 (1996), and clarified in *State Farm Mutual Automobile Insurance Co. v. Campbell*, 538 U.S. 408 (2003).

The Roundtable is an association of the chief executive officers of approximately 150 member companies with a combined workforce of more than 10 million employees in the United States and about $4 trillion in revenues. The executives who created the Roundtable believed that the U.S. economy would be healthier, there would be less unwarranted intrusion by government into business affairs, and the interest of the public would be better served if the business sector were to play an active and effective role in public affairs. The Roundtable's participation as *amicus* is consistent with its overall goal of representing the views of its membership before all branches of government on important matters affecting the business sector.

Amici are concerned that the Oklahoma Court of Civil Appeal's approval of a $10 million punitive damages award against the manufacturer of a nationally distributed, federally regulated and approved product exemplifies the continued, erroneous application of *Gore* and *State Farm* in the critically important field of products liability law, not only because the lower court completely abdicated its responsibility to prevent the assessment of punitive damages based on out-of-state conduct that was beyond the constitutional authority of Oklahoma to regulate, but because the lower court failed to perform the searching scrutiny required to ensure that a jury-imposed sanction comports with due process limitations on proportionality. *Amici* are uniquely positioned to assist the Court in this case because their members are subject to, and directly affected by, a tort system that threatens manufacturers and sellers of federally regulated and nationally distributed products with ruinous liability, and they have a fundamental interest in the articulation and enforcement of rules that promote reasoned and properly guided decision-making by judges and juries alike.

Accordingly, the Chamber and the Roundtable respectfully request that this Court grant leave to file the attached *amici curiae* brief.

Respectfully submitted,

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INTEREST OF *AMICI CURIAE*

The Chamber of Commerce of the United States of America (the "Chamber") is the nation's largest federation of business companies and associations, with an underlying membership of more than 3,000,000 businesses and professional organizations of every size and in every sector and geographic region of the country.[1] Because the fair administration of punitive damages long has been a concern of the business community, the Chamber regularly files *amicus* briefs in punitive damages cases.

The Business Roundtable (the "Roundtable") is an association of the chief executive officers of approximately 150 member companies with a combined workforce of more than 10 million employees in the United States and about $4 trillion in revenues. The executives who created the Roundtable believed that the U.S. economy would be healthier, there would be less unwarranted intrusion by government into business affairs, and the interest of the public would be better served if the business sector were to play an active and effective role in public affairs. The Roundtable's participation as *amicus* is consistent with its overall goal of representing the views of its membership before all branches of government on important matters affecting the business sector.

Amici have a particular concern with widespread and growing efforts to impose punitive damages in products liability cases involving nationally distributed products based on a manufacturer's single design or labeling decision (or similar course of action) which is alleged to have affected all end users indiscriminately. These efforts threaten massive and potentially crippling punitive damage impositions as individual juries are

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[1] A motion for leave to file an *amici curiae* brief is attached hereto. Pursuant to Supreme Court Rule 37.6, *amici curiae* declare that no counsel for any party to this case authored this brief in whole or in part and that no entity or person, other than *amicus* the Chamber, its members, and its counsel, made any monetary contribution to the preparation or submission of this brief.

repeatedly requested not only to "punish and deter" the same alleged misconduct, but to assess punitive awards based in whole or in part on the totality of alleged injury caused by that misconduct. If unchecked, the mere threat of such overlapping punitive damages awards violates Constitutional due process standards by impairing defendants' positions in financial markets and compromising their ability to defend even before liability is adjudicated. In the current punitive damages environment, unproven allegations that a product is implicated in a mass tort are enough to cause severe economic disruption for the manufacturer, pushing down stock prices, disrupting contractual relationships with third parties, and raising borrowing costs.

In *BMW of North America, Inc. v. Gore*, 517 U.S. 559 (1996) and *State Farm Mutual Automobile Insurance Co. v. Campbell*, 538 U.S. 408 (2003), this Court articulated due process guideposts and limitations on punitive damages awards, including extraterritoriality limitations, which have somewhat ameliorated the problem presented by runaway punitive damages. It is *amici*'s experience, however, that state reviewing courts often have misapplied and effectively nullified the *Gore* and *State Farm* principles.[2] Indeed, on appeal from the trial court's judgment, Respondent appears to have succeeded in persuading the Oklahoma Court of Civil Appeals that the principles announced in *Gore* and *State Farm* should be limited to the unique facts of those cases. Thus, *amici* seek to have this Court reinforce the *Gore* and *State Farm* principles and to give additional consideration to their specific adaptation in the context of products liability cases, with particular attention to the substantial potential that punitive damages awarded in such

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[2] See Appellees' Brief in Response at 27, *Wakefield v. Warner-Lambert Co.*, No. 99,086 (Okla. Dec. 29, 2003) (arguing that "*Gore* . . . only applies to illegal conduct that resulted in a *purely economic* injury" and *State Farm* "does not apply . . . because the [extraterritorial] conduct penalized in that case bore no relation to the Campbells' claims in particular" (emphasis in original)).

cases will not only raise excessiveness concerns but unduly burden interstate commerce.

REASONS FOR GRANTING THE PETITION

This case provides a paradigmatic vehicle for addressing the issues raised by punitive damages in products liability cases. It involves a product, Rezulin®, which was distributed nationally by Petitioner Warner-Lambert Company under uniform design specifications and labeling approved, as required by federal law, by the Federal Food and Drug Administration ("FDA").[3] Notwithstanding that approval, Respondent (plaintiff below) was permitted to challenge both the propriety of Warner-Lambert's distribution of the product and the adequacy of Warner-Lambert's labeling under Oklahoma's general tort law standards. The jury was allowed to assess whether Petitioners' interactions with the FDA in securing marketing approval warranted an imposition of punitive damages. The jury was further permitted by Oklahoma law and urged by Respondent's counsel to assess punitive damages based on Petitioners' alleged worldwide profits from sales of Rezulin®. The $10 million punitive award was indisputably based on these worldwide profits.

As shown below, the award clearly violated the territoriality teachings of *Gore* and *State Farm* by sanctioning Petitioners' sales activity outside Oklahoma without any finding that such conduct was unlawful under the law of any other jurisdiction. In addition, the award does not foreclose the pursuit of similar awards based on the same conduct and the same alleged profits by the many plaintiffs claiming Rezulin® injury in other States. The jury's $10 million punitive sanction, approximately 6.5 times the jury's $1.55 million compensatory award, thus raises issues of excessiveness under the standards set forth in *Gore* and *State Farm*, as well as substantial, related questions of cumulative burden on interstate commerce.

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[3] Petitioner Warner-Lambert Co. is a wholly owned subsidiary of Petitioner Pfizer Inc.

It is vitally important that the Court clarify that lower courts cannot endorse the imposition of multiple, excessive, and duplicative sanctions arising out of the design and marketing of nationally regulated and distributed products without any regard to whether the defendant's conduct (1) is unlawful in other jurisdictions; or (2) has been (or should have been) punished previously.[4] Accordingly, the petition for certiorari should be granted to provide essential guidance on the proper application of *Gore* and *State Farm* in the products liability field.

I. Certiorari Should Be Granted Because The Lower Court Flouted This Court's Rulings By Affirming A $10 Million Punitive Damages Award That Considered Out-Of-State Sales Absent Any Showing That Such Sales Were Unlawful

The lower court's affirmance of a $10 million punitive damages award based on out-of-state sales of Warner-Lambert's FDA-approved drug Rezulin® squarely contravenes this Court's holdings in *Gore* and *State Farm*.

At the liability phase of the trial, there was no evidence that Warner-Lambert's conduct was motivated by personal *animus* or otherwise specifically directed to the injured party. Instead, the jury was presented with evidence bearing on the inherent qualities of the product, alleged defects in the product labeling, and Warner-Lambert's allegedly wrongful conduct in securing FDA approval. Following the presentation of the evidence, the jurors were instructed under Oklahoma law, see R. 3821, Tr. at 3228:5-7, to consider theories of negligence, strict products liability based on defective design or labeling, and deceit. R. 3821, Tr. at 3230:15-3240:15. The jurors were further instructed that, if they returned a verdict for the plaintiffs,

[4] The last decision of this Court to address the application of due process limitations to punitive damage awards in a products liability case involving a defendant's undifferentiated conduct in marketing a federally regulated, nationally marked product was *Honda Motor Co. v. Oberg*, 512 U.S. 415 (1994), a case that pre-dated the refinement of the Court's analytical approach in *Gore* and *State Farm*.

they were also required to determine whether plaintiffs had established by clear and convincing evidence that "Warner-Lambert Company acted in a reckless disregard of the rights of others and/or acted intentionally and with malice towards others." R. 3821, Tr. at 3242:1-5.

The jury returned a verdict of $1.55 million in actual damages, and further found "by clear and convincing evidence that Warner-Lambert Company acted in reckless disregard of the rights of others" and "acted intentionally and with malice toward others," R. 3823, Tr. at 3385:6-15, triggering the punitive damages phase of the trial. Under Oklahoma law, the jury was permitted to award punitive damages of the magnitude affirmed below only if the jury (1) considered seven statutorily enumerated factors that bear on a defendant's level of culpability and financial condition; (2) found by "clear and convincing evidence that . . . defendant has acted intentionally and with malice towards others;" and (3) further determined that, in the circumstances presented, the appropriate measure of punitive damages was an amount "not to exceed . . . the increased financial benefit derived by the defendant . . . as a direct result of the conduct causing the injury to the plaintiff and other persons or entities." Okla. Stat. tit. 23, § 9.1(C) (2002). Neither the Oklahoma statute nor the trial court judge, however, imposed any geographical limitations on the jury's consideration of the foregoing criteria. Specifically, over Petitioners' objections, R. 3823, Tr. at 3387:25-3389:20, the trial judge refused to provide the jury with *any* guidance regarding the constitutional limitations on their ability to impose a financial penalty based on Petitioners alleged involvement in "misconduct" outside the State of Oklahoma, on the alleged "profitability of the misconduct," or on the "financial benefit derived by [Petitioners] . . . as a direct result of the conduct. . . ." Okla. Stat. tit. 23, §§ 9.1(A)(1)-(2), (C) (1) (c) (2002).

Instead, the trial court judge read the jurors excerpts of the Oklahoma statute *verbatim*, which included a general instruction that the jury should consider "the profitability of the misconduct

to the defendant," R. 3823, Tr. at 3402:1-2, and instructed them that, using "sound reason," they were permitted to consider and award punitive damages in an amount less than or equal to "the increased financial benefit derived by the defendant as a direct result of the conduct that caused injury to the plaintiff," and to "grant the plaintiff punitive damages in such sum as you reasonably believe will punish the defendant and be an example to others." R. 3823, Tr. at 3401:8-3402:23. Seizing upon this opening, Respondent's trial counsel made no effort to confine her presentation to the financial consequences of Petitioners' conduct in Oklahoma, but urged the jury to calculate Warner-Lambert's "financial benefit" based on the undifferentiated, worldwide revenue figures reflected in Petitioners' annual reports:

> If you find . . . that this company acted not just recklessly but with intent, then you may award either twice the actual damages you have already awarded, *or the increased financial benefit to this company from the drug Rezulin.* That is what the [Oklahoma] statute allows you, that's what the Court has instructed you. *You can now look at how much money they made, profit, profit, financial benefit from the drug Rezulin.*
>
> So if you look at the annual reports, you will see that they had Rezulin profit in '97, '98 and '99. And we know from what Dr. Maloney testified to that they were looking at a greater than 30 percent profit margin on this drug. . . .
>
> *So the profit, the financial profit . . . of this drug to this company over these three years is $600 million. That's the profit from what they did. The profit from Rezulin over the five weeks that Michael Wakefield took the drug. . . . in that five-week time period Warner-Lambert Parke-Davis makes $21 million in profit on the drug. . . .*
>
> *So when* you *look at the financial benefit, . . . just the profit is a range of $21 million, which is the first*

> *five weeks he's on it . . . all the way to $600 million, which is the three-year profit that this company made off this drug.* It's a little technical when you read the annual reports, but if you have any question as to the benefits, the increase in stock price, the increase in income, the net sales or how much they earned on Rezulin alone, go back and look at the annual reports. . . .

R. 3823, Tr. at 3409:17-3411:3 (emphases added).

It is difficult to overstate the due process concerns that pervade a trial process that permits a lay jury to impose punitive damages in a single tort case somewhere in the vast divide between no recovery and $600 million based on worldwide revenue figures. The trial court's refusal to impose any geographical limitation on the jury's deliberations at the punitive damages phase invalidated the $10 million punitive damages verdict, because notwithstanding that the jury's finding of compensatory liability was necessarily limited to a determination that Petitioners' conduct was wrongful solely under Oklahoma law, the jury's punitive damages calculation was permitted to roam worldwide. Whatever relevance Warner-Lambert's out-of-state acts may have had to determining (1) Warner-Lambert's liability for actual damages; or (2) plaintiffs' eligibility to recover punitive damages,[5] the introduction of such evidence should

[5] In *Gore*, this Court observed that, though it was "error for the jury to use the number of sales in other States as a multiplier in computing the amount of its punitive sanction," evidence of such sales "may be relevant to the determination of the degree of reprehensibility of the defendant's conduct." *BMW of N. Am., Inc. v. Gore*, 517 U.S. 559, 574 n.21 (1996). In light of the Court's subsequent observation in *State Farm* that "as a general rule, . . . a State [does not] have a legitimate concern in imposing punitive damages to punish a defendant for unlawful acts committed outside of the State's jurisdiction," 538 U.S. at 421, it is questionable whether the Court's observation in *Gore* retains any vitality. In any event, absent carefully drawn and enforced limiting instructions, it is clear that evidence of out-of-state acts may influence a jury's mathematical calculation at the punitive damages phase of the trial.

have been policed carefully to ensure that it was not misused to calculate the amount of the sanction to avoid expanding the regulatory impact of a punitive damages award beyond the State's inherent authority to regulate. *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 420-22 (2003). Here, it was plainly improper to permit the jury to consider Petitioners' sales of Rezulin® outside of Oklahoma in fixing the dollar amount of the punitive damages award.

In *Gore*, while reserving on the question whether there is any circumstance in which "one State may properly attempt to change a tortfeasor's *unlawful* conduct in another State," *BMW of North America, Inc. v. Gore*, 517 U.S. 559, 573 n.20 (1996), this Court made clear that a State has no authority to base a state law punitive damages award on a tortfeasor's *lawful* conduct in another State:

> As the Alabama Supreme Court noted, neither the jury nor the trial court was presented with evidence that any of BMW's out-of-state conduct was unlawful. . . . The Alabama Supreme Court therefore properly eschewed reliance on BMW's out-of-state conduct, . . . and based its remitted award solely on conduct that occurred within Alabama. The award must be analyzed in the light of the same conduct, with consideration given only to the interests of Alabama consumers, rather than those of the entire Nation.

Id. at 573-74 (footnote and citations omitted). The Court reiterated and expanded upon this proposition in *State Farm*:

> A State cannot punish a defendant for conduct that may have been lawful where it occurred. . . . Nor, as a general rule, does a State have a legitimate concern in imposing punitive damages to punish a defendant for unlawful acts committed outside of the State's jurisdiction. Any proper adjudication of conduct that occurred outside Utah to other persons would require their inclusion, and, to those parties, the Utah courts,

> in the usual case would need to apply the laws of their relevant jurisdiction.

538 U.S. at 421-22 (citations omitted). Thus, as *Gore* and *State Farm* recognize, implicit in a state-by-state, case-by-case approach to the adjudication of tort liability is the principle that the law of one State cannot be invoked to punish a defendant for the financial consequences of conduct that took place outside of the State.

The State of Oklahoma has no conceivable, "legitimate interest" in punishing conduct (let alone lawful conduct) that occurs beyond its borders, and may not "use the punitive damages deterrent as a means of imposing its regulatory policies on the entire Nation." *Gore*, 517 U.S. at 568, 585; *see id.* at 571 ("one State's power to impose burdens on the interstate market . . . is not only subordinate to the federal power over interstate commerce, . . . but is also constrained by the need to respect the interest of other States") (citations omitted); *State Farm*, 538 U.S. at 421 (noting that State laws cannot be permitted to operate beyond State boundaries "'without throwing down the constitutional barriers by which all the States are restricted within the orbits of their lawful authority and upon the preservation of which the Government under the Constitution depends'") (citation omitted). Here, irrespective of the evidence that was introduced at trial relevant to the FDA approval process for Rezulin®, there was no attempt to demonstrate (let alone to ask the jury to find) that Petitioners' conduct was *unlawful* in any State *other than Oklahoma*. Once the jury returned a verdict of compensatory damages under Oklahoma law, however, there was no effort to confine the broader financial implications of the jury's verdict to Petitioners' conduct *within Oklahoma*. Though Petitioners specifically raised these issues on appeal, Appellants' Brief in Chief at 26-28, *Wakefield v. Warner-Lambert Co.*, No. 99,086 (Okla. Nov. 7, 2003); Appellants' Reply Brief at 22-25, *Wakefield v. Warner-Lambert Co.*, No. 99,086 (Okla. Jan. 20, 2004), the Oklahoma Court of Civil Appeals brushed Petitioners' arguments aside with the conclusory and manifestly

erroneous observation that the punitive damages award did "no[t] attempt[] to sanction Manufacturing Defendants for conduct legal in other states." Pet. App. at 18.

The lower court's refusal to acknowledge the bright-line, geographical limitations that bound punitive damages awards in the wake of *Gore* and *State Farm* unfairly threatens product manufacturers in at least four ways. *First*, because plaintiffs outside of Oklahoma are not bound by its judgment, the lower court's approach creates a grave risk of excessive, multiple punishments for the same conduct causing the exact same harms.[6] It is fundamentally unfair to allow a plaintiff in an individual case to collect punitive damages for conduct that affects different parties in other states, while subsequent juries in other states remain free to impose punishment for the very same conduct. As this Court explained in the context of an *in rem* action in which the Commonwealth of Pennsylvania claimed entitlement to certain funds under its escheat statute, a property owner "is deprived of due process of law if he is compelled to relinquish it without assurance that he will not be held liable again in another jurisdiction or in a suit brought by a claimant who is not bound by the first judgment." *W. Union*

[6] Ironically, the pertinent provisions of the Oklahoma statute provide that "[t]he trial court shall reduce any award for punitive damages . . . by the amount it finds the defendant . . . has previously paid as a result of all punitive damage verdicts *entered in any court of this state* for the same conduct by the defendant." Okla. Stat. tit. 23, § 9.1(C)(1)(c) (2002) (emphasis added) (Pet. App. at 23-24). The court below failed to address Petitioners' argument that – consistent with these terms – the Oklahoma statute limits the permissible scope of the jury's consideration to the impact of a defendant's conduct *in Oklahoma*. Appellants' Brief in Chief at 27, *Wakefield v. Warner-Lambert Co.*, No. 99,086 (Okla. Nov. 7, 2003). Regardless of how the Oklahoma statute should be interpreted as a matter of State law, however, the set-off provision only protects Petitioners from duplicative punitive damage awards by other Oklahoma courts. It does not relieve Petitioners from the threat of punitive damage awards outside of Oklahoma that are based in whole or in part on the same worldwide financial figures that were provided to the Tulsa jury.

Co. v. Pennsylvania, 368 U.S. 71, 75 (1961). *See also Ex Parte Lange*, 85 U.S. (18 Wall.) 163, 168-69 (1873) (describing "the maxim" in civil cases "that no man shall be twice vexed for one and the same cause"). That, however, is precisely the situation when a jury in an individual case is permitted to impose punitive damages that are unrelated to the injury to the plaintiff on the theory that the defendant committed other bad acts against individuals who are not before the court. *See Roginsky v. Richardson-Merrell, Inc.*, 378 F.2d 832, 839-40 (2d Cir. 1967) (Friendly, J.) (describing multiple-punishment problem); *Juzwin v. Amtorg Trading Corp.*, 718 F. Supp. 1233, 1235-36 (D.N.J. 1989) ("multiple awards of punitive damages for a single course of conduct violate the fundamental fairness requirement of the Due Process Clause," but there is no effective, nationwide remedy absent "Supreme Court decision or national legislation"). *See also Allied-Signal, Inc. v. Director, Div. of Taxation*, 504 U.S. 768, 777-78 (1992) (State must apportion taxes to the share of the income fairly attributable to the taxpayers' business within the State.).

Though the legal prohibition against multiple civil punishments has deep roots, until recently the issue was largely academic. In *Roginsky* – one of the first decisions to highlight the "destructive synergism between traditional punitive damages doctrine and modern mass tort litigation" (John Calvin Jeffries, Jr., *A Comment on the Constitutionality of Punitive Damages*, 72 Va. L. Rev. 139, 141 (1986)) – Judge Friendly noted that punitive damages had their genesis in intentional torts, in which "usually there is but a single victim; a punitive recovery by him ends the matter, except for such additional liability as may be provided by the criminal law." *Roginsky*, 378 F.2d at 838. That paradigm, however, was completely eclipsed in the last half century by the advent of mass tort litigation. *See* Jeffries, *supra*, 72 Va. L. Rev. at 141-43. In the case of a nationally distributed product, "punitive damages may be repetitively invoked against a single course of conduct in unfair and potentially ruinous aggregation." *Id.* at 139; see *Roginsky*, 378 F.2d at 839.

Second, by permitting the jury to assess punitive damages based on out-of-state sales in the absence of any evidence that such sales were unlawful in the jurisdictions in which they occurred, the lower court failed to account for the fact that other juries (or courts or regulators) considering precisely the same conduct might conclude that Petitioners did nothing wrong or, at least, that the conduct did not warrant punishment.[7] Until it was voluntarily withdrawn from the market by Petitioners, Rezulin® was an FDA-approved drug that was widely used with beneficial results for diabetes patients. *E.g.*, R. 3797, Tr. at 1778:25-1779:10; R. 3798, Tr. at 1836:9-25, Tr. at 1882:5-19, Tr. at 1884:2-10. Because the judgment in an individual case brought against a manufacturer that distributes its products nationwide is not binding on anyone other than the plaintiff, however, the lower court's "punish for everything" approach unfairly invites the repeated assessment of overlapping "percentage of net profit" punishments with potentially devastating consequences divorced from any rational notion of deterrence.[8]

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[7] In opposition to Petitioners' appeal below, Respondent baldly asserted that Warner-Lambert's "misconduct was illegal in every state," Appellees' Brief in Response at 27, *Wakefield v. Warner-Lambert Co.*, No. 99,086 (Okla. Dec. 29, 2003), but Respondent offered no record support for this assertion because there is none.

[8] Further compounding the lower courts' error, a major feature of Respondent's case-in-chief at trial was that Warner-Lambert had committed a fraud on the FDA by withholding critical information during the regulatory approval process and that, as a consequence, Warner-Lambert had been permitted to market a drug that never should have received federal approval in the first place. *See, e.g.*, Pet. App. at 3; R. 3821, Tr. at 3269:10-3285:17. As this Court made clear in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 348 (2001), however, "state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by, federal law." Even assuming that, post-*Buckman*, it is permissible for a plaintiff to introduce alleged evidence of fraud-on-the-FDA in support of state common law claims sounding generally in strict products liability and deceit, it is impossible to reconcile

(Cont'd)

Third, by abdicating its constitutional responsibility to impose appropriate limits on the jury's discretion, the lower court elevated the jury to the position of a *de facto* national regulator, passing judgment on, and doling out punishment for, the marketing of Rezulin® throughout the United States and beyond. Though our legal system long has recognized a lay jury's competence to decide specific factual issues relating to the claims of the parties before it, there is no basis for concluding that a lay jury has the expertise and resources to act as a super-regulator. In this case, the trial court's refusal to instruct the jury on the proper limitations of its role permitted the jury to impose fact-bound judgments rendered pursuant to Oklahoma law and the standards of the Tulsa community on Petitioners' conduct in the world at large. Simply put, the jury was permitted to sanction Petitioners for out-of-state sales in the absence of

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(Cont'd)

Respondent's reliance on *national sales* of an FDA-approved drug at the punitive damages phase of the trial with the reasoning of *Buckman*:

> State-law fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives. As a practical matter, complying with the FDA's detailed regulatory regime in the shadow of 50 States' tort regimes will dramatically increase the burdens facing potential applicants – burdens not contemplated by Congress in enacting the FDCA and the MDA. . . .
>
> [F]raud-on-the-FDA claims would also cause applicants to fear that their disclosures to the FDA, although deemed appropriate by the Administration, will later be judged insufficient in state court. Applicants would then have an incentive to submit a deluge of information that the Administration neither wants nor needs. . . .

Id. at 350, 351. Here, in the absence of proper limiting instructions, the jury effectively was permitted not only to consider Respondent's fraud-on-the-FDA theory under the rubric of Oklahoma law, but to punish Petitioners under Oklahoma law for "financial benefits" obtained on a nationwide (and, indeed, worldwide) basis.

any competent legal or evidentiary grounds for a reasoned judgment about the lawfulness or unlawfulness of Petitioners' conduct beyond Oklahoma's borders.

Fourth, the unfairness inherent in the lower court's approach is magnified by the burden that it imposes upon a corporate defendant in an individual tort case to defend not only against the underlying cause of action, but also against an amorphous "smear campaign" that seeks to penalize the defendant for the financial consequences of out-of-state conduct in the absence of any showing that the extraterritorial conduct was unlawful. Here, notwithstanding that the jury's finding of compensatory liability was based solely on the application of Oklahoma law, the jury was permitted to impose punitive damages on Petitioners based on sales of Rezulin® worldwide. This put Petitioners in an impossible position because, though it is a plaintiff's burden under Oklahoma law to prove a right to recover punitive damages by clear and convincing evidence, once the trial court allowed worldwide revenues into the equation there was no effective way that Petitioners could rebut Respondent's enormous, back-of-the-envelope punitive damages calculation. By forcing the corporate defendants into this position, the trial court tipped the litigation playing field dramatically and unjustifiably in plaintiffs' favor.

II. Certiorari Should Be Granted Because, Contrary To This Court's Precedents, The Lower Court Failed To Conduct Any Meaningful *De Novo* Review In Response To Petitioners' Arguments That The $10 Million Punitive Damages Award Was Excessive

In *Cooper Industries, Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424, 436 (2001), this Court held that appellate courts must conduct a *de novo* review to ensure that a trial court's award of punitive damage comports with the three excessiveness guideposts laid down in *Gore*: degree of reprehensibility, ratio, and (where applicable) sanctions for comparable misconduct. *Gore*, 517 U.S. at 575-85. The Court reiterated that mandate in *State Farm*, observing that "[e]xacting appellate review ensures

that an award of punitive damages is based upon an application of law, rather than a decisionmaker's caprice." 538 U.S. at 418 (internal quotation marks and citation omitted). In neither *Cooper Industries* nor *State Farm*, however, did the Court instruct lower courts as to the precise meaning of "exacting" review in the context of determining whether the punishment is commensurate with the *Gore* factors.

In the instant case, from all that appears on the face of the decision below, the Oklahoma Court of Civil Appeals either misapprehended or ignored the gravamen of Petitioners' constitutional objections to the punitive damages award. On appeal, Petitioners argued at length, among other things, that (1) the trial court improperly permitted the punitive damages award to be based on out-of-state sales in the absence of any showing that such sales were unlawful; and (2) that the award was excessive. Appellants' Brief in Chief at 26-29; Appellants' Reply Brief at 22-29. On the first point, Petitioners argued that the jury should not have been permitted to "consider[] . . . conduct that did *not* cause any injury, such as Warner-Lambert's sales to people who benefitted greatly from Rezulin and experienced no ill effect," and that because the jury was permitted to rely on "*worldwide gross sales* of Rezulin as the measure of Warner-Lambert's increased financial benefit, the jury's punitive award violated the statutory and constitutional requirement that only the impact of the Defendant's conduct in *Oklahoma* may be considered in assessing punitive damages." Appellants' Brief in Chief at 26-27. On the second point, Petitioners argued that the punitive damages award was obviously excessive because it was based on revenue figures that had nothing to do with Oklahoma and disproportionate in its own right. *Id.* at 28-29.

In response to these arguments – and notwithstanding Respondent's concession that the jury was "presented . . . with a wide range of numbers to consider for punitive damages: $600 million in worldwide sales to $21 million [in worldwide sales] during just the five (5) weeks that Wakefield took

Rezulin," Appellees' Brief in Response at 27 – the court below offered nothing more than a conclusory and manifestly erroneous rebuttal:

> Manufacturing Defendants do not specifically elucidate how the result of this case violates either of these principles, and we find it does not. The punitive damages award in this case neither reflects a grossly excessive award, nor attempts to sanction Manufacturing Defendants for conduct legal in other states.

Pet. App. at 18.

The lower court's refusal to exercise any meaningful supervisory role over the jury's award resulted in a clear miscarriage of justice. *First*, an appellate court cannot simply rubber-stamp a punitive damages award in the absence of any discernible evidence that the award comports with constitutional norms. *See Honda Motor Co. v. Oberg*, 512 U.S. 415, 432 (1994) (rejecting arguments that jury instructions provided defendant with sufficient protection against arbitrary imposition of punitive damages, and holding that appellate review is "one of the few procedural safeguards which the common law provide[s] against that danger"). Here, though the jury could not possibly have reached the $10 million figure without considering the "increased financial benefit derived by the defendant" (R. 3823, Tr. at 3402:1-2, 15-20), the record was completely bereft of any evidence that would have permitted the jury to tie the $10 million to the "increased financial benefit" that Warner-Lambert derived in Oklahoma. Beyond concluding that the jury's award was necessarily based on some consideration of the "increased financial benefit" cap in the Oklahoma statute, any argument about the basis for the jury's calculation is purely speculative, because the figure might as well have been pulled out of thin air. *See Gore*, 517 U.S. at 593-94 (Breyer, J., concurring) ("[C]ourts properly tend to judge the rationality of judicial actions in terms of the reasons that were given, and the facts that were before the court, . . . not those that might have been

given on the basis of some conceivable set of facts. . . ."); *TXO Produc. Corp. v. Alliance Res. Corp.*, 509 U.S. 443, 486 (1993) (O'Connor, J., dissenting) ("[D]ue process does not simply require that a particular result be substantively acceptable; it also requires that it be reached on the basis of permissible considerations.").

Second, though this Court has not yet considered the question, the proportionality concerns voiced in *Gore* and *State Farm* are heightened where, as here, a case does not involve a particularized course of conduct directed specifically at the plaintiff, but a generalized course of conduct that resulted in the widespread distribution of a product in interstate commerce. In *State Farm*, the threat of duplicative punitive damage awards was sharply reduced by virtue of the fact that, at the core, plaintiffs' case was about State Farm's handling of an insurance claim on its unique facts. 538 U.S. at 412-15, 419. In this case, by contrast, the jury passed judgment under Oklahoma law on the lawfulness of Warner-Lambert's conduct in securing regulatory approval and marketing an FDA-approved drug. Warner-Lambert had no personal contact with the injured party or his representatives until suit was commenced, and Warner-Lambert's conduct vis-à-vis the injured party was indistinguishable from its conduct in designing and marketing the product nationally.

Without impugning a successful tort plaintiff's entitlement to recover compensatory damages, *amici* submit that the historical rationale for allowing punitive damage awards (let alone substantial awards) is largely if not entirely lacking in cases like the one at bar. Historically, punitive damages were typically reserved for cases involving intentional torts directed at a single victim. *Roginsky*, 378 F.2d at 838. Furthermore, because punitive damages are about deterrence and not compensation, they are intended to "serve the same purposes as criminal penalties," *State Farm*, 538 U.S. at 417, at least partly out of a concern that, if the defendant is not adequately punished with civil liability, its conduct will escape any other government

sanction. Where mass torts in the products liability field are concerned, however, these historical rationales collapse. As Judge Friendly observed:

> We have the gravest difficulty in perceiving how claims for punitive damages in such a multiplicity of actions throughout the nation can be so administered as to avoid overkill. . . . We know of no principle whereby the first punitive award exhausts all claims for punitive damages and would thus preclude future judgments. . . .
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> * * *
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> While jurisprudes might comprehend why Toole in California should walk off with $250,000 more than a compensatory recovery and Roginsky in the Southern District of New York and Mrs. Ostopowitz in Westchester County with $100,000, most laymen and some judges would have some difficulty in understanding why presumably equally worthy plaintiffs . . . elsewhere in the country should get less or none.
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> [I]f we were sitting as the highest court of New York we would wish to consider very seriously whether awarding punitive damages with respect to the negligent – even highly negligent – manufacturer and sale of a drug governed by federal food and drug requirements . . . and the present vigorous attitude toward enforcement, would not do more harm than good. A manufacturer distributing a drug to many thousands of users under government regulation scarcely requires this additional measure for manifesting social disapproval and assuring deterrence. Criminal penalties and heavy compensatory damages, recoverable under some circumstances even without proof of negligence, should sufficiently meet these

> objectives, and the other factors cited as justifying punitive damage awards are lacking.

Roginsky, 378 F.2d at 839-41. In cases that arise out of generalized, undifferentiated conduct that implicates the rights of private parties nationwide, whatever freedom a State court enjoys to invoke common law tort principles to regulate the conduct of corporate actors within the State's borders must be tempered by the recognition that the State court is not operating in a vacuum.

In such a case – and where, as here, "compensatory damages are substantial" – *amici* respectfully submit that a punitive damages ratio "equal to compensatory damages . . . can reach" – if not substantially exceed – "the outermost limit of the due process guarantee." *State Farm*, 538 U.S. at 425. This is particularly so because of the substantial direct and indirect burdens that the threat of unrestrained, repetitive punitive damage awards impose on interstate commerce. If individual State courts are permitted to impose enormous financial penalties on product manufacturers by punishing out-of-state conduct, the threat embedded in this unlawful form of extraterritorial regulation will burden manufacturers' activities nationwide. Furthermore, unless and until manufacturers of nationally distributed products are provided with additional safeguards against the runaway imposition of overlapping punitive damage awards, manufacturers will be discouraged from bringing beneficial products to market despite a federal regulatory environment that recognizes that the benefits associated with certain products outweigh the risks. The *ratio decidendi* reflected in the decision below is not only intellectually divorced from the traditional rationales that have been offered for the imposition of extraordinary sanctions, but threatens to substitute corporate destruction for corporate deterrence.

Third, *Gore* and *State Farm* teach that where compensatory damages are substantial (here, $1.55 million), punitive damages ordinarily should not exceed compensatory damages except in cases of highly reprehensible conduct. The *State Farm* Court emphasized the "long legislative history, dating back over 700 years and going

forward to today, providing for sanctions of double, treble, or quadruple damages" and indicated that, although such ratios "are not binding, they are instructive." 538 U.S. at 425. "When compensatory damages are substantial, then a lesser ratio, perhaps only equal to compensatory damages, can reach the outermost limit of the due process guarantee," and ratios as high as 4 to 1 are "close to the line of constitutional impropriety." *Id.* Here, the lower court's affirmance of a 6.5 to 1 sanction should not be permitted to stand not only because the award was founded on constitutionally impermissible evidence of out-of-state revenue, but because the lower court failed to conduct any meaningful, *de novo* proportionality analysis. Even assuming that there were some evidentiary basis to support the Oklahoma jury's heavy imposition on a federally regulated and approved product (which there is not), *Gore* and *State Farm* plainly require that a reviewing court do more than the Oklahoma Court of Civil Appeals undertook to do in this case.

CONCLUSION

For all of the foregoing reasons and for the reasons set forth in the petition, the Court should grant the petition on the questions presented and reverse the decision of the Oklahoma Court of Civil Appeals.

Respectfully submitted,

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